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10/598,366	12/20/2006	**Dennis Blum**	53000 PCT US	3205

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EXAMINER	
KASHNIKOW, ERIK	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
04/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,366	BLUM ET AL.	
	Examiner	Art Unit	
	ERIK KASHNIKOW	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 9 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1, 2 and 6-9 of U.S. Patent No. 7,086,403. Although the conflicting claims are not identical, they are not patentably distinct from each other because for claims 1-3 the only difference is that the instant claims say the lubricant is for heat, while the patents claims state that the lubricant is for desensitizing, however as they are comprised of the same materials their physical and chemical properties would intrinsically be the same. It is further pointed out that the disclosure of 44 and 68.2% polypropylene glycol falls within the range of at least 10% required in the instant claims. With regards to claims 4-5 it has been shown that absent

a showing of criticality with respect to "concentration of polyethylene glycol" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "concentration of polyethylene glycol" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In regards to claim 9 it has been shown that absent a showing of criticality with respect to "amount of lubricant applied to inner and outer layer" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "amount of lubricant on the inner and outer layer" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). While the patent does not disclose the condom being packaged, it would have been obvious to one of ordinary skill in the art at the time of the invention to package the condom in order to preserve its effectiveness.

Claims 1-6 and 9 directed to an invention not patentably distinct from claim1,2 and 6-9 of commonly assigned 7,086,483. Specifically, see the reasons above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 7,086,483, discussed above, would form the basis

for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-3 rejected under 35 U.S.C. 102(a) as being anticipated by Harrison et al. (US 2002/0103414).

4. In regards to claims 1 and 3 Harrison et al. teach a condom with lubrication, wherein the lubrication comprises 44% or 68.2% propylene glycol (claims 8 and 9). While there is no disclosure that the lubricant is a warmth inducing lubricant as

presently claimed, given that Harrison et al. disclose lubrication composition identical to that claimed and comprising propylene glycol in amounts claimed, it is clear that the lubricating composition would inherently warm upon contact with compositions containing free water. Claim 12 teaches an embodiment wherein the condom is packaged.

5. In regards to claim 2 Harrison et al. teach a lubricant containing the glycol applied to the inner and outer surface of the sheath (paragraphs 0009 and 0010).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (US 2002/0103414).

8. As discussed above Harrison et al. teach a condom with lubricant disposed on both sides, however they are silent regarding concentrations of polyethylene glycol above 30% and the amount of lubricant applied to the condom and the condom being packaged.

9. With regards to claims 4-5, while Harrison et al. teach propylene glycol used with polyethylene glycol (claims 8 and 9) they are silent with regards to concentrations of propylene glycol being over 30%, however it has been shown that absent a showing of

criticality with respect to "concentration of polyethylene glycol" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "concentration of polyethylene glycol" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. In regards to claim 6 and 8 Harrison et al. teach the inclusion of glycol polymethacrylate (claim 8 and claim 9).

11. In regards to claim 9 it has been shown that absent a showing of criticality with respect to "amount of lubricant applied to inner and outer layer" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the "amount of lubricant on the inner and outer layer" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Claims 1-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791) in view of Ahmad et al. (US 2003/0211161).

13. In regards to claim 1 Lezdey et al. teach a lubricant designed to give heat applied to a condom (claim 9) wherein the lubricant is comprised of a glycol (column 5 lines 15-

30). One of ordinary skill in the art at the time of the invention would recognize that a condom is a tubular sheath designed to engage the male genitals.

14. As stated above Lezdey et al. teach a condom with lubricant designed to give heat applied therein however they are silent with regards to the condom being packaged, propylene glycol, and polyethylene glycol, as well as amounts of each compound and amount of lubricant applied to the condom.

15. In regards to the condom being packaged, it is well known to one of ordinary skill in the art at the time of the invention would have known it to be obvious to package a condom when not in use, in order to preserve said condom.

16. In regards to claim 2 and the limitation wherein the lubricant is being applied to both the inner and outer sheath Lezdey et al. teach that the lubricant is designed to impart heat to the body part at the sight of application, as there are two body parts involved in normal condom usage it would be obvious to one of ordinary skill in the art at the time of the invention to apply the lubricant so that it imparts a heat sensation to both body parts involved, and therefor to coat the inner and outer surface of the sheath.

17. In regards to claims 3-5 Ahmad et al. teach lubricants for use with vaginal or oral mucosa which is intended to generate a warm feeling (paragraph 0001). Ahmad et al. teach that the lubricant comprise over 10% of propylene glycol, and over 30% polyethylene glycol ([0038], page 10 second column compositions 10-13).

18. In regards to claim 9 it has been shown that absent a showing of criticality with respect to "amount of lubricant applied to inner and outer layer" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of

the invention to adjust the "amount of lubricant on the inner and outer layer" through routine experimentation to values, including those presently claimed in order to achieve "an effective lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

19. One of ordinary skill in the art at the time of the invention would be motivated to modify the invention of Lezdey et al. with that of Ahmad et al. because the invention of Ahmad et al. is non irritating and is more lubricating then other known warming lubricants (paragraph 0001).

20. Claims 6-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (US 6,428,791) in view of Ahmad et al. (US 2003/0211161) as applied to claim 5 above and further in view of Harrison et al. (US 2002/0103414).

21. As stated above Lezdey et al. and Ahmad et al. teach condoms with lubricants that give a warming sensation, however they are silent with regard to glyceryl polymethacrylate.

22. Harrison et al. teach condoms with lubrication applied therein (Abs).

23. In regards to claim 6 Harrison et al. teach that glyceryl polymethacrylate may be added to lubricants containing polyethylene and propylene glycols (claim 8).

24. In regards to claim 7 Ahmad et al. teach the inclusion of glycerin in the lubricants (paragraph 0062).

25. While Lezdey et al. Ahmad et al. and Harrison et al. are silent with regards to the specific composition in claim 8 it has been shown that absent a showing of criticality with respect to "concentrations of polyethylene and propylene glycol, glycerin and a mixture of glyceryl polymethacrylate, propylene glycol and water" (a result effective variable), it would have been obvious to a person of ordinary skill in the art at the time of the invention to adjust the " concentrations of polyethylene and propylene glycol, glycerin and a mixture of glyceryl polymethacrylate, propylene glycol and water " through routine experimentation to values, including those presently claimed in order to achieve "an effective condom lubricant". It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

26. One of ordinary skill in the art at the time of the invention would be motivated to modify the invention of Lezdey et al. and Ahmad et al. with that of Harrison et al. because the invention of Harrison et al. offers increased insurance that the lubricant stays on the condom during packaging and shipping (paragraph 0020).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIK KASHNIKOW whose telephone number is (571)270-3475. The examiner can normally be reached on Monday-Friday 7:30-5:00PM EST (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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